

SUPPORT FOR THE AMENDMENTS

Claim 26 is added.

Claim 26 is supported by paragraph [0009] and previously presented Claim 1.

No new matter is believed to have been added by this amendment.

REMARKS

Claims 1-26 are pending in the present application.

The rejection of Claims 1-3 and 5-25 under 35 U.S.C. §112, second paragraph, is respectfully traversed.

The Examiner has now rejected Claims 1-3 and 5-25 as being indefinite due to the limitation that the chelating agent is at an amount of “0.1% by weight or less”. The Examiner alleges this limitation is unclear because this phrasing permits for the chelating agent to be “not present” or present in any amount not to exceed 0.1%, including “0.0001%”. The Examiner is precisely correct in that the claims do, and were intended to, embrace any amount of chelating agent that is 0.1% by weight or less including “zero” (i.e., not present). There is certainly nothing unclear about this limitation and the language is facially understandable. Thus, this ground of rejection is without merit.

Withdrawal of this ground of rejection is requested.

The rejections of Claims 1-3, 5-10, and 12-25 under 35 U.S.C. §103(a) over Forward (US 4,193,988) in combination with Lee (US 6,214,321) and Claim 11 under 35 U.S.C. §103(a) over Forward (US 4,193,988) in combination with Lee (US 6,214,321) and Takatsuka (US 7,300,645) are respectfully traversed.

Paragraphs 5-6 of the Office Action are verbatim copies of paragraphs 7-8 of the Office Action mailed June 2, 2011. In paragraph 7 of the Office Action, the Examiner presents an explanation as to why the rejections have been maintained. Applicants disagree with these rejections for the reasons that follow restating the response filed October 4, 2010, and further addressing the Examiner’s allegations in maintaining the rejections.

The present application describes an invention in which a chelating agent (e.g., citrate) is preferably not substantially added. In this aspect of the invention, *avoiding* the chelating agent prevents the decrease of calcium ion concentration. This in turn allows improved remineralization of teeth (see paragraphs [0012] and [0016] of the PG publication (i.e., US 2007/0128131)).

The Forward patent describes a different composition; namely, a composition in which pH is controlled by *adding* substances such as citric acid (see column 2, lines 62-65 of the Forward patent). Forward does not appreciate and does not disclose the difficulties encountered when sodium monofluorophosphate is used in combination with calcium glycerophosphate and thus does not appreciate the chelate-avoidance aspect of the present invention. Applicants on the other hand disclosed the difficulties associated with using sodium monofluorophosphate in admixture with a calcium ion-supplying compound (see for example paragraphs [0003] and [0011] of the PG publication).

Citric acid in particular binds strongly to calcium ions to thereby chelate the calcium ion and make the calcium unavailable for the purpose of remineralizing teeth. The invention described in the present claims avoids this undesirable function of chelation by requiring that chelating agents such as citrate (e.g., a salt or ester derived from citric acid) are included in an amount of no more than 0.1 wt%. This requirement of the present claims is directly contradictory to the Forward disclosure in which citric acid (e.g., a progenitor of the citrate chelating agent) is added to control pH (see column 4, second paragraph of Forward).

Applicants disclosed a composition which permits the stable supply of calcium ions for the remineralization of teeth by using a particular acid to control the pH to 4-6.2. Forward describes modifying the acidity of compositions with an acid agent (e.g., citrate). In

contrast, the present claims restrict the amount of chelating agent (e.g., citrate) to no more than 0.1%.

With respect to the relative amount of the chelating agents which may be present in the claimed composition, Applicants further draw the Office's attention to previously pending Claim 10 which describes a composition having 0.01% by weight or less of the chelating agent.

Applicants submit that the Office's allegation of obviousness is not supportable at least for the reason that the Forward patent fails to disclose or suggest the invention presently disclosed and claimed.

Lee fails to remedy the defects of Forward. It is an explicit requirement of the present claims that the claimed composition is "homogeneous". Lee describes a composition that must be in separate parts (see the Abstract of Lee). Importantly, at least one of the components of the Lee composition must have a pH that is outside of the pH range recited in the present claims (see the Abstract of Lee). Further, even if the separate portions of the Lee composition were combined, the resulting composition would violate the "homogeneous" requirement of the present claims because hydroxyapatite precipitates (see the Abstract of Lee).

Lee further discloses that citrate chelating agents are useful for sequestering ferric/ferrous ion (see column 5, lines 12-23 of Lee). Contrary to suggesting the exclusion of chelating agents in the manner of the present claims, Lee encourages the inclusion of chelating agents for the purpose of sequestering certain ions.

Those of skill in the art reading Lee in view of Forward would have no reason to believe that the presently claimed homogeneous composition could be derived from a modification of Forward in the manner of Lee.

With respect to the arguments above related to the chelating agent limitation, the Examiner apparently interprets this argument to relate to the absolute exclusion of chelating agents noting that the art reads on amounts of chelating agents of 0.1%. Regardless, this limitation is not taken as being a point of distinction, at least, in view of the lack of a chelating agent in the examples disclosed by Forward at columns 3-4.

Despite this allegation by the Examiner, this limitation is relevant to the extent that neither Forward nor Lee recognize the problem associated with the presence of chelating agents, including citrate. The discovery of a problem is often the key to making a patentable invention. Thus, the patentability of an invention under 35 U.S.C. §103 must be evaluated against the background of the highly developed and specific art to which it relates, and this background includes an understanding of those unsolved problems persisting in the art solved by the invention. *See, Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 43 S.Ct. 322, 67 L.Ed. 523 (1923). To this end, Forward discloses that citric acid (e.g., a progenitor of citrate) is a preferred acidifying agent and Lee discloses that citric acid and sodium acid citrate are among the preferred acidifying agents. Thus, following the guidance of Forward and Lee, the artisan would not be lead to the claimed invention. Indeed, they would have no reason to identify recognize the problems associated with the presence of chelating agents, including citrate.

Of greater significance to the chelating agent limitation is that lack of a disclosure in Forward of the inclusion of lactic acid, malic acid, and tartaric acid. The Examiner openly acknowledges this deficiency, but maintains that this limitation is satisfied by Lee. Specifically, the Examiner alleges that Lee shows an equivalence between citric acid and lactic acid, malic acid, and tartaric acid, thus providing motivation for the modification. Applicants disagree and maintain that Lee fails to remedy the defects of Forward.

Indeed, the claims require that the claimed composition is “homogeneous”. Lee describes a composition that must be in separate parts (see the Abstract of Lee). The first composition containing the calcium phosphate salt is disclosed as having an acidic pH (see column 3, lines 10-38). The acidic pH is achieved by the use of an acidifying agent including citric acid, lactic acid, malic acid, and tartaric acid (see column 4, lines 9-20). The second composition includes a fluoride anticaries compound and an alkaline material (see column 3, lines 39-61). Thus, the guidance proffered by Lee is not to replace the citric acid with lactic acid, malic acid, and tartaric acid as the Examiner alleges, but rather to separate the calcium phosphate salt and the anticaries compound into two *distinct* compositions.

Moreover, if the separate portions of the Lee composition were combined, the resulting composition would violate the “homogeneous” requirement of the present claims because hydroxyapatite precipitates (see the Abstract of Lee). In fact, this is the specific objective of Lee to achieve deposition of the hydroxyapatite on the dental enamel. In other words, the mode of operation in Lee is directly in conflict with that of the claimed invention and would not lend itself to the modification of Forward as alleged by the Examiner.

Moreover, Lee further discloses that citrate chelating agents are useful for sequestering ferric/ferrous ion (see column 5, lines 12-23 of Lee). Again, this disclosure suggests the inclusion of chelating agents which is to be excluded in the claimed invention. In other words, contrary to suggesting the exclusion of chelating agents in the manner of the present claims, Lee encourages the inclusion of chelating agents for the purpose of sequestering certain ions. Thus, if Lee is read together with Forward as the Examiner suggests, the result would be (i) separation of the oral hygiene composition into two discrete compositions and (ii) to add citrate chelating agents.

Thus, for the reasons above, the claimed invention is not obvious over Forward and Lee, even if viewed with Takatsuka (only cited teaching oral compositions for remineralization including silicic anhydride).

Further, the Examiner is reminded that at least Claims 5, 12, 14, 15, 16, and 17 describe embodiments of this aspect of the invention in terms of resistance to the precipitation of calcium-containing materials. Such properties are directly contradictory to the properties of the Lee compositions, i.e., the generation and deposition of hydroxyapatite. Applicants thus submit that the aforementioned claims are further patentable over the cited art.

Claims 22-23 describe compositions in which the calcium ion-supplying compound is present in a greater amount than the monofluorophosphate ion-supplying compound. Claims 22 and 23 are further patentable over the combination of Forward and Lee for the reason that Forward describes compositions in which a calcium-containing material is present in substantially greater amounts than a monofluorophosphate-containing compound, i.e., a composition in which sodium monofluorophosphate and calcium glycerophosphate are present in relative amounts of 10:1 to 3:1. In Lee the sodium monofluorophosphate is present in substantially greater amounts than the calcium glycerophosphate (see the Abstract of Forward). New Claims 24 and 25 further define the relative amounts of the monofluorophosphate ion-supplying and calcium ion-supplying compounds of the present claims.

Claims 20 and 21 are likewise further patentable over the cited art. Where Forward describes a pH range that is 6 or greater (see column 2, lines 62-65), Claims 20 and 21 describe pH ranges that do not include a pH of 6. Applicants thus submit that Claims 20 and 21 are further patentable over the cited art.

In view of the foregoing, withdrawal of these grounds of rejection are requested.

For the reasons discussed above in detail, Applicants respectfully request withdrawal of the rejection and the allowance of all now-pending claims.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, L.L.P.



Richard L. Treanor
Attorney of Record
Registration No. 36,379

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/09)

Vincent K. Shier, Ph.D.
Registration No. 50,552